



DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 3 2001

Food and Drug Administration
Rockville MD 20857

David Moll
President and CEO
International Laboratory Technology Corporation
3389 Sheridan Street, Suite 149
Hollywood, Florida 33021

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Re: Docket No. 75N-183H/CP3 and SUP4

Dear Mr. Moll:

This letter is sent in reference to your citizen petition dated April 6, 2000, and a supplement to that petition dated November 16, 2000. The petition and supplement are filed as CP3 and SUP4, respectively, in Docket No. 75N-183H in FDA's Dockets Management Branch. The petition requests that FDA amend the Tentative Final Monograph (TFM) for Over-the-Counter (OTC) Health-care Antiseptic Drug Products (June 17, 1994, 59 FR 31402) to include benzalkonium chloride (0.11 to 0.13 percent) as a generally recognized safe and effective active ingredient for use in OTC antiseptic handwash products. This letter also responds to your recent facsimile dated February 12, 2001, requesting written assurance that the agency intends to include benzalkonium chloride in the final monograph.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR §10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR §10.30(e).

Your petition is one of a number of petitions requesting amendment of the TFM. The agency is in the process of evaluating the petitions and comments submitted to the public docket and their impact on the development of a final rule for OTC health-care antiseptic drug products. Consequently, we are unable to provide a final decision on the merits of your request within 180 days of the date your request was filed. However, resolution of the pending petitions for this rulemaking are important, and a response to your petition will be provided at a later date. As we have not completed our evaluation of the data, we cannot provide any indication of the status of benzalkonium chloride in the final monograph.

If you have any questions regarding this matter please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

75N-183H

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cc: HFD-1
HFA-305 (Docket No. 75N-183H/CP3)
HFD-7/Petition file
HFD-105:Rdelapp/Jbull RS 3/23/01
HFD-310
HFD-312
HFD-560: CGanley/LKatz/GRachanow/DLumpkins/BMerritt/OTC file Health care
Antiseptic Drug Products

RD: DLumpkins/2-26-01
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Edited: GRachanow/2/28/01
FT: CGanley/DLumpkins/3/12/01

OTC TIRON No. 2455